

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

[illegible]

[Caption Continues on Next Page]

**DEFENDANTS MYLAN LABORATORIES INC., MYLAN PHARMACEUTICALS INC.  
AND UDL LABORATORIES, INC.'S ANSWER AND AFFIRMATIVE DEFENSES TO  
PLAINTIFFS' REVISED FIRST AMENDED CONSOLIDATED COMPLAINT**

<i>County of Cortland v. Abbott Laboratories, Inc., et al.</i> (N.D.N.Y. No. 05-CV-00881)	)	
<i>County of Dutchess v. Abbott Laboratories, Inc., et al.</i> (S.D.N.Y. No. 05-CV-06458)	)	
<i>County of Essex County v. Abbott Laboratories, Inc., et al.</i> (N.D.N.Y. No. 05-CV-00878)	)	
<i>County of Fulton v. Abbott Laboratories, Inc., et al.</i> (N.D.N.Y. No. 05-CV-00519)	)	
<i>County of Genesee v. Abbott Laboratories, Inc., et al.</i> (W.D.N.Y. No. 05-CV-06206)	)	
<i>County of Greene v. Abbott Laboratories, Inc., et al.</i> (N.D.N.Y. No. 05-CV-00474)	)	
<i>County of Herkimer v. Abbott Laboratories, Inc., et al.</i> (N.D.N.Y. No. 05-CV-00415)	)	
<i>County of Jefferson v. Abbott Laboratories, Inc., et al.</i> (N.D.N.Y. No. 05-CV-00715)	)	
<i>County of Lewis v. Abbott Laboratories, Inc., et al.</i> (N.D.N.Y. No. 05-CV-00839)	)	
<i>County of Madison v. Abbott Laboratories, Inc., et al.</i> (N.D.N.Y. No. 05-CV-00714)	)	
<i>County of Monroe v. Abbott Laboratories, Inc., et al.</i> (W.D.N.Y. No. 05-CV-06148)	)	
<i>County of Nassau v. Abbott Laboratories, Inc., et al.</i> (E.D.N.Y. No. 04-CV-5126)	)	
<i>County of Niagara v. Abbott Laboratories, Inc., et al.</i> (W.D.N.Y. No. 05-CV-06296)	)	
<i>County of Oneida v. Abbott Laboratories, Inc., et al.</i> (N.D.N.Y. No. 05-CV-00489)	)	
<i>County of Onondaga v. Abbott Laboratories, Inc., et al.</i> (N.D.N.Y. No. 05-CV-00088)	)	
<i>County of Ontario v. Abbott Laboratories, Inc., et al.</i> (W.D.N.Y. No. 05-CV-06373)	)	
<i>County of Orange v. Abbott Laboratories, Inc., et al.</i> (S.D.N.Y. No. 07-CV-2777)	)	
<i>County of Orleans v. Abbott Laboratories, Inc., et al.</i> (W.D.N.Y. No. 05-CV-06371)	)	
<i>County of Putnam v. Abbott Laboratories, Inc., et al.</i> (S.D.N.Y. No. 05-CV-04740)	)	

[Caption Continues on Next Page]

<i>County of Rensselaer v. Abbott Laboratories, Inc., et al.</i> (N.D.N.Y. No. 05-CV-00422)	)	
<i>County of Rockland v. Abbott Laboratories, Inc., et al.</i> (S.D.N.Y. No. 03-CV-7055)	)	
<i>County of Saratoga v. Abbott Laboratories, Inc., et al.</i> (N.D.N.Y. No. 05-CV-00478)	)	
<i>County of Schuyler v. Abbott Laboratories, Inc., et al.</i> (W.D.N.Y. No. 05-CV-06387)	)	
<i>County of Seneca v. Abbott Laboratories, Inc., et al.</i> (W.D.N.Y. No. 05-CV-06370)	)	
<i>County of St. Lawrence v. Abbott Laboratories, Inc., et al.</i> (N.D.N.Y. No. 05-CV-00479)	)	
<i>County of Steuben v. Abbott Laboratories, Inc., et al.</i> (W.D.N.Y. No. 05-CV-06223)	)	
<i>County of Suffolk v. Abbott Laboratories, Inc., et al.</i> (E.D.N.Y. No. CV-03-229)	)	
<i>County of Tompkins v. Abbott Laboratories, Inc., et al.</i> (N.D.N.Y. No. 05-CV-00397)	)	
<i>County of Ulster v. Abbott Laboratories, Inc., et al.</i> (N.D.N.Y. No. 06-CV-0123)	)	
<i>County of Warren v. Abbott Laboratories, Inc., et al.</i> (N.D.N.Y. No. 05-CV-00468)	)	
<i>County of Washington v. Abbott Laboratories, Inc., et al.</i> (N.D.N.Y. No. 05-CV-00408)	)	
<i>County of Wayne v. Abbott Laboratories, Inc., et al.</i> (W.D.N.Y. No. 05-CV-06138)	)	
<i>County of Westchester v. Abbott Laboratories, Inc., et al.</i> (S.D.N.Y. No. 03-CV-6178)	)	
<i>County of Wyoming v. Abbott Laboratories, Inc., et al.</i> (W.D.N.Y. No. 03-CV-6379)	)	
and	)	
<i>County of Yates v. Abbott Laboratories, Inc., et al.</i> (W.D.N.Y. No. 05-CV-06172)	)	

Defendants Mylan Laboratories Inc., Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc. (collectively, “Mylan”), by their undersigned attorneys, as and for their Answer to Plaintiffs’ Revised First Amended Consolidated Complaint (“Consolidated Complaint”), dated June 8, 2007 but filed on October 5, 2007 (Docket No. 4780), state as follows:

Mylan states that it is answering Plaintiffs’ allegations solely on behalf of itself, and only to the extent Plaintiffs’ allegations concern the alleged actions of Mylan, even when Plaintiffs’ allegations refer collectively to alleged conduct by Mylan and other persons or entities or refer to alleged conduct by “defendants” without further definition. To the extent the allegations in the Consolidated Complaint refer to the alleged knowledge, conduct or actions of other persons or entities, Mylan is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

Mylan specifically denies any allegations contained in headings, footnotes, or unnumbered paragraphs in the Consolidated Complaint.

Mylan responds to the individual numbered paragraphs of the Consolidated Complaint as follows:

1. Mylan denies the allegations in Paragraph 1 of the Consolidated Complaint, including the allegations contained in the referenced Exhibit B, except admits that the Counties purport to bring this action as alleged and Mylan further admits that Exhibit B to the Consolidated Complaint purports to identify the prescription drugs at issue in this action.

2. Mylan denies the allegations in Paragraph 2 of the Consolidated Complaint and refers the Court to the referenced statutes for a full and complete statement of their terms except that Mylan denies knowledge or information sufficient to form a belief as to

the truth of the allegations contained in Exhibit A of the Consolidated Complaint and, therefore, denies those allegations.

3. Mylan denies the allegations in Paragraph 3 of the Consolidated Complaint and refers the Court to the referenced statutes and regulatory materials for a full and complete statement of their terms.

4. Mylan denies the allegations in Paragraph 4 of the Consolidated Complaint.

5. Mylan denies the allegations in Paragraph 5 of the Consolidated Complaint and refers the Court to the referenced regulation for a full and complete statement of its terms.

6. Mylan denies the allegations in Paragraph 6 of the Consolidated Complaint and refers the Court to the referenced statutes for a full and complete statement of their terms.

7. Mylan denies the allegations in Paragraph 7 of the Consolidated Complaint and refers the Court to the referenced statute for a full and complete statement of its terms.

8. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 8 of the Consolidated Complaint and, therefore, denies those allegations.

9. Mylan denies the allegations in Paragraph 9 of the Consolidated Complaint.

10. Mylan denies the allegations in Paragraph 10 of the Consolidated Complaint except Mylan admits that, at certain times, Mylan Pharmaceuticals Inc. and UDL

Laboratories, Inc. provided certain pricing information to certain price reporting compendia for certain drugs.

11. Mylan denies the allegations in Paragraph 11 of the Consolidated Complaint.

12. Mylan denies the allegations in Paragraph 12 of the Consolidated Complaint, including the allegations contained in the referenced Exhibit F.

13. Mylan denies the allegations in the first sentence of Paragraph 13 of the Consolidated Complaint. Mylan denies the allegations in the second and third sentences of Paragraph 13 and refers the Court to the referenced regulation for a full and complete statement of its terms. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the fourth and fifth sentences of Paragraph 13 and, therefore, denies those allegations.

14. Mylan denies the allegations in Paragraph 14 of the Consolidated Complaint.

15. Mylan denies the allegations in Paragraph 15 of the Consolidated Complaint, including the allegations contained in the referenced Exhibit B.

16. Mylan denies the allegations in Paragraph 16 of the Consolidated Complaint.

17. Mylan denies the allegations in Paragraph 17 of the Consolidated Complaint.

18. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 18 of the Consolidated Complaint and, therefore, denies those allegations.

19. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 19 of the Consolidated Complaint and, therefore, denies those allegations.

20. Mylan denies the allegations in Paragraph 20 of the Consolidated Complaint and refers the Court to the referenced article for a full and complete statement of its contents.

21. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 21 of the Consolidated Complaint and, therefore, denies those allegations. Mylan denies the allegations in the second sentence of Paragraph 21.

22. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 22 of the Consolidated Complaint and, therefore, denies those allegations.

23. Mylan denies the allegations in Paragraph 23 of the Consolidated Complaint.

24. Mylan denies the allegations in the first sentence of Paragraph 24 of the Consolidated Complaint. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the second, third, fourth and fifth sentences of Paragraph 24 and, therefore, denies those allegations.

25. Mylan denies the allegations in the first and second sentences of Paragraph 25 of the Consolidated Complaint. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the third sentence of Paragraph 25

and, therefore, denies those allegations. Mylan denies the allegations in the fourth sentence of Paragraph 25.

26. Mylan denies the allegations in Paragraph 26 of the Consolidated Complaint and refers the Court to the referenced report for a full and complete statement of its contents.

27. Mylan denies the allegations in Paragraph 27 of the Consolidated Complaint and refers the Court to the referenced congressional hearing transcript for a full and complete statement of its contents.

28. Mylan denies the allegations in Paragraph 28 of the Consolidated Complaint, including the allegations contained in the referenced Exhibit B.

29. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the first, third and fourth sentences of Paragraph 29 of the Consolidated Complaint and, therefore, denies those allegations. Mylan denies the allegations in the second, fifth and sixth sentences of Paragraph 29 of the Consolidated Complaint.

30. Mylan denies the allegations in Paragraph 30 of the Consolidated Complaint, including the allegations contained in the referenced Exhibit B.

31. Mylan denies the allegations in Paragraph 31 of the Consolidated Complaint and refers the Court to the referenced statutes for a full and complete statement of their terms.

32. Mylan denies the allegations in Paragraph 32 of the Consolidated Complaint.



33. Mylan denies the allegations in the first sentence of Paragraph 33 of the Consolidated Complaint. Mylan denies the allegations in the second sentence of Paragraph 33 and refers the Court to the referenced statute for a full and complete statement of its terms.

34. Mylan denies the allegations in Paragraph 34 of the Consolidated Complaint and refers the Court to the referenced report for a full and complete statement of its contents.

35. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 35 of the Consolidated Complaint and, therefore, denies those allegations.

36. Mylan denies the allegations in the first sentence of Paragraph 36 of the Consolidated Complaints, including the allegations contained in the referenced Exhibit D, except Mylan admits that certain states have filed actions against Mylan alleging meritless and ill-formed claims similar to those in this action and Mylan further admits that it has responded to government subpoenas and written requests for information without any admission or finding of fault or liability. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations the second, third, fourth, fifth, sixth, seventh, and eighth sentences in Paragraph 36 of the Consolidated Complaint and, therefore, denies those allegations, except admits that Exhibit D purports to be a list of investigations and lawsuits against certain defendants. Mylan denies the allegations in the ninth sentence of Paragraph 36 of the Consolidated Complaint except admits that Exhibit D purports to be a list of investigations and lawsuits against certain defendants.

37. Mylan denies the allegations in Paragraph 37 of the Consolidated Complaint except admits Plaintiffs seek the recovery alleged.

38. Mylan denies the allegations in Paragraph 38 of the Consolidated Complaint except admits Plaintiffs assert claims as alleged.

39. Mylan denies the allegations in Paragraph 39 of the Consolidated Complaint.

40. Mylan denies the allegations in Paragraph 40 of the Consolidated Complaint.

**Parties**

41 – 56. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 41 through 56 of the Consolidated Complaint and, therefore, denies those allegations.

57. Mylan denies the allegations in Paragraph 57 of the Consolidated Complaint, except admits that Dey, Inc. and Dey, L.P. do business at 2751 Napa Valley Corporate Drive, Napa, CA 94558 and that Dey, L.P. is engaged in the business of manufacturing and selling pharmaceuticals.

58 – 69. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 58 through 69 of the Consolidated Complaint and, therefore, denies those allegations.

70 (a). Mylan denies the allegations in Paragraph 70 (a) of the Consolidated Complaint except admits that Mylan Laboratories Inc. is a Pennsylvania corporation whose principal place of business is located at 1500 Corporate Drive, Canonsburg, Pennsylvania, 15317.

70 (b). Mylan admits the allegations in Paragraph 70 (b) of the Consolidated Complaint.

70 (c). Mylan denies the allegations of Paragraph 70 (c) of the Consolidated Complaint except admits that UDL Laboratories (“UDL”) is a wholly owned subsidiary of Mylan Laboratories Inc. and is an Illinois corporation whose principal place of business is located at 1718 Northrock Court, Rockford, Illinois 61103 and further admits that UDL engages in the business of selling pharmaceuticals.

71 – 88. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 71 – 88 of the Consolidated Complaint and, therefore, denies those allegations.

89 – 98. Mylan denies the allegations in Paragraphs 89 – 98 of the Consolidated Complaint and refers the Court to the referenced statutes and regulations for a full and complete statement of their terms.

99. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 99 of the Consolidated Complaint, including those allegations contained in the referenced Exhibit B, and, therefore, denies those allegations.

100. Mylan denies the allegations in Paragraph 100 of the Consolidated Complaint, except admits that prescription drugs in the United States are assigned a National Drug Code (“NDC”) and further admits that the United States Food and Drug Administration publishes NDCs for each of the dosage forms and package sizes of a prescription drug.

101. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 101 of the Consolidated Complaint and, therefore, denies those allegations. Mylan denies the allegations in the second sentence of Paragraph 101 and refers the Court to the referenced list for a full and complete statement of its contents.

102. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 102 of the Consolidated Complaint and, therefore, denies those allegations.

103. Mylan denies the allegations in Paragraph 103 of the Consolidated Complaint and refers the Court to the referenced list for a full and complete statement of its contents.

104. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 104 of the Consolidated Complaint and, therefore, denies those allegations.

105. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 105 of the Consolidated Complaint and, therefore, denies those allegations.

106. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 106 of the Consolidated Complaint and, therefore, denies those allegations.

107. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 107 of the Consolidated Complaint and, therefore, denies those allegations.

108. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 108 of the Consolidated Complaint and, therefore, denies those allegations.

109. Mylan denies the allegations in Paragraph 109 of the Consolidated Complaint and refers the Court to the relevant statutes establishing and governing the New York

Medicaid Program for a full and complete statement of the rules governing claims submitted by providers for prescription drugs.

110. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 110 of the Consolidated Complaint and, therefore, denies those allegations.

111. Mylan denies the allegations in the first sentence of Paragraph 111 of the Consolidated Complaint and refers the Court to the referenced statute for a full and complete statement of its terms. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence of Paragraph 111 and, therefore, denies those allegations.

112. Mylan denies the allegations in the first sentence of Paragraph 112 of the Consolidated Complaint except admits that certain publishing services publish and report AWP. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence of Paragraph 112, and, therefore, denies those allegations.

113. Mylan denies the allegations in the first sentence of Paragraph 113 of the Consolidated Complaint. Mylan denies the allegations in the second sentence of Paragraph 113, except admits that certain provisions of the Medicaid rebate statute provided that reported average manufacturer prices would be confidential. Mylan denies the allegations in the third sentence of Paragraph 113 and refers the Court to the referenced transcript of the congressional hearing for a full and complete statement of its contents.

114. Mylan denies the allegations in Paragraph 114 of the Consolidated Complaint and refers the Court to the referenced report for a full and complete statement of its contents.

115. Mylan denies the allegations in Paragraph 115 of the Consolidated Complaint and refers the Court to the referenced report for a full and complete statement of its contents.

116 – 127. Mylan denies the allegations in Paragraph 116 – 127 of the Consolidated Complaint and refers the Court to the referenced statutes and legislative history for a full and complete statement of their terms.

128. Mylan denies the allegations in Paragraph 128 of the Consolidated Complaint and refers the Court to the relevant statutes for a full and complete statement of their terms.

129. Mylan denies the allegations in Paragraph 129 of the Consolidated Complaint and refers the Court to the referenced brief and statute for a full and complete statement of their terms.

130. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 130 of the Consolidated Complaint and, therefore, denies those allegations.

131. Mylan denies the allegations in Paragraph 131 of the Consolidated Complaint and refers the Court to the referenced agreement for a full and complete statement of its terms.

132. Mylan denies the allegations in Paragraph 132 of the Consolidated Complaint, except admits that it entered into a rebate agreement with the Secretary of Health and Human Services and refers the Court to that agreement for a full and complete statement of its terms.

133 – 136. Mylan denies the allegations in Paragraph 133 – 136 of the Consolidated Complaint and refers the Court to the referenced agreement for a full and complete statement of its terms.

137. Mylan denies the allegations in the first sentence of Paragraph 137 of the Consolidated Complaint and refers the Court to the referenced statutes for a full and complete statement of their terms. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the second, third and fourth sentences of Paragraph 137 and, therefore, denies those allegations.

138. Mylan denies the allegations in Paragraph 138 of the Consolidated Complaint and refers the Court to the referenced statute for a full and complete statement of its terms.

139. Mylan denies the allegations in Paragraph 139 of the Consolidated Complaint and refers the Court to the referenced statute for a full and complete statement of its terms.

140. Mylan denies the allegations in Paragraph 140 of the Consolidated Complaint and refers the Court to the referenced statute for a full and complete statement of its terms.

141. Mylan denies the allegations in Paragraph 141 of the Consolidated Complaint and refers the Court to the referenced statute for a full and complete statement of its terms.

142. Mylan denies the allegations in Paragraph 142 of the Consolidated Complaint and refers the Court to the referenced brief for a full and complete statement of its contents.

143. Mylan denies the allegations in Paragraph 143 of the Consolidated Complaint.

144. Mylan denies the allegations in Paragraph 144 of the Consolidated Complaint, except admits that, at certain times, Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc. provided certain pricing information to certain price reporting compendia for certain drugs.

145. Mylan denies the allegations in the first sentence of Paragraph 145 of the Consolidated Complaint except admits that Exhibit B purports to identify the prescription drugs at issue. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence of Paragraph 145 and, therefore, denies those allegations. Mylan denies the allegations in the third sentence of Paragraph 145, except admits that Exhibit B purports to allege certain information regarding the prescription drugs at issue.

146. Mylan denies the allegations in Paragraph 146 of the Consolidated Complaint, except admits that Exhibit B purports to allege certain information regarding the prescription drugs at issue.

147. Mylan denies the allegations in Paragraph 147 of the Consolidated Complaint.

148. Mylan denies the allegations in Paragraph 148 of the Consolidated Complaint.

149. Mylan denies the allegations in Paragraph 149 of the Consolidated Complaint.

150. Mylan denies the allegations in Paragraph 150 of the Consolidated Complaint, except admits that Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc. were



aware, at various times, of the prices at which certain of their products were sold to providers and were aware, at various times, that FULs applied to certain generic products.

151. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 151 of the Consolidated Complaint and, therefore, denies those allegations.

152. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 152 of the Consolidated Complaint and, therefore, denies those allegations. Mylan denies the allegations in the second and third sentences of Paragraph 152 of the Consolidated Complaint.

153. Mylan denies the allegations in Paragraph 153 of the Consolidated Complaint.

154. Mylan denies the allegations in Paragraph 154 of the Consolidated Complaint and refers the Court to the referenced HHS OIG publication for a full and complete statement of its content.

155. Mylan denies the allegations in Paragraph 155 of the Consolidated Complaint except it admits that, from time to time, Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc. offered prompt payment discounts, rebates and credits and that such prompt pay discounts, rebates and credits were not used to set some reported prices.

156. Mylan denies the allegations in Paragraph 156 of the Consolidated Complaint except admits that Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc. control their discounting policies.

157. Mylan denies the allegations in Paragraph 157 of the Consolidated Complaint except admits that, from time to time, Mylan Pharmaceuticals Inc. and UDL

Laboratories, Inc. offered prompt payment discounts, rebates and credits and that such prompt pay discounts, rebates and credits were not used to set some reported prices.

158. Mylan denies the allegations in Paragraph 158 of the Consolidated Complaint.

159. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 159 of the Consolidated Complaint and, therefore, denies those allegations.

160. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 160 of the Consolidated Complaint and, therefore, denies those allegations.

161. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 161 of the Consolidated Complaint and, therefore, denies those allegations. Mylan denies the allegations in the second sentence of Paragraph 161 and refers the Court to the referenced article for a full and complete statement of its content.

162. Mylan denies the allegations in Paragraph 162 of the Consolidated Complaint and refers the Court to the referenced article for a full and complete statement of its content.

163. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 163 of the Consolidated Complaint and, therefore, denies those allegations.

164. Mylan denies the allegations in Paragraph 164 of the Consolidated Complaint except admits that Plaintiffs purport to set forth an example.

165. Mylan denies the allegations in Paragraph 165 of the Consolidated Complaint and refers the Court to the referenced report for a full and complete statement of its content.

166. Mylan denies the allegations in Paragraph 166 of the Consolidated Complaint.

167. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 167 of the Consolidated Complaint and, therefore, denies those allegations.

168. Mylan denies the allegations in Paragraph 168 of the Consolidated Complaint, but admits Mylan has executed a rebate agreement with the Secretary of Health and Human Services and refers the Court to that agreement for a full and complete statement of its terms.

169. Mylan denies the allegations in Paragraph 169 of the Consolidated Complaint and refers the Court to the referenced agreement for a full and complete statement of its terms.

170. Mylan denies the allegations in Paragraph 170 of the Consolidated Complaint.

171. Mylan denies the allegations in Paragraph 171 of the Consolidated Complaint.

172. Mylan denies the allegations in the first sentence of Paragraph 172 of the Consolidated Complaint. Mylan denies the allegations in the second sentence of Paragraph 172 and refers the Court to the referenced agreement for a full and complete statement of its terms. Mylan denies the allegations in the third sentence of Paragraph 172.

173. Mylan denies the allegations in the first sentence of Paragraph 173 of the Consolidated Complaint. Mylan denies the allegations in the second sentence of Paragraph 173 and refers the Court to the referenced statute for a full and complete statement of its terms. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the third and fourth sentences of Paragraph 173, and, therefore, denies those allegations.

174. Mylan denies the allegations in Paragraph 174 of the Consolidated Complaint and refers the Court to the referenced report for a full and complete statement of its contents.

175. Mylan denies the allegations in Paragraph 175 of the Consolidated Complaint except admits that, from time to time, Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc. use various lawful and industry-standard inducements to stimulate sales of their products.

176. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 176 of the Consolidated Complaint and, therefore, denies those allegations.

177. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 177 of the Consolidated Complaint and, therefore, denies those allegations, except Mylan admits that it has responded to government subpoenas and written requests for information without any admission or finding of fault or liability.

178. Mylan denies the allegations in the first sentence of Paragraph 178 of the Consolidated Complaint, except Mylan admits that it has responded to government subpoenas and written requests for information without any admission or finding of fault or liability. Mylan

denies the allegations in the second sentence of Paragraph 178 and refers the Court to the referenced letter for a full and complete statement of its terms.

179. Mylan denies the allegations in Paragraph 179 of the Consolidated Complaint and refers the Court to the referenced letter for a full and complete statement of its content.

180. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 180 of the Consolidated Complaint and, therefore, denies those allegations. Mylan denies the allegations in the second, third and fourth sentences of Paragraph 180 and refers the Court to the referenced congressional hearing transcript for a full and complete statement of its contents. Mylan denies the allegations in the fifth sentence of Paragraph 180, except admits that Exhibit A purports to identify certain prescription drugs at issue in this action.

181. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 181 of the Consolidated Complaint and, therefore, denies those allegations. Mylan denies the allegations in the second sentence of Paragraph 181 of the Consolidated Complaint and refers the Court to the referenced letter for a full and complete statement of its contents.

182. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 182 of the Consolidated Complaint and, therefore, denies those allegations.

183. Mylan denies the allegations in Paragraph 183 of the Consolidated Complaint and refers the Court to the relevant portions of the letter for a full and complete statement of its content.

184. Mylan denies the allegations in Paragraph 184 of the Consolidated Complaint and refers the Court to the referenced letter for a full and complete statement of its content.

185. Mylan denies the allegations in Paragraph 185 of the Consolidated Complaint and refers the Court to the relevant portions of the referenced Congressional Record for a full and complete statement of its contents.

186. Mylan denies the allegations in Paragraph 186 of the Consolidated Complaint and refers the Court to the referenced report for a full and complete statement of its content.

187. Mylan denies the allegations in Paragraph 187 of the Consolidated Complaint and refers the Court to the referenced report for a full and complete statement of its content.

188. Mylan denies the allegations in Paragraph 188 of the Consolidated Complaint and refers the Court to the referenced report for a full and complete statement of its content.

189. Mylan denies the allegations in Paragraph 189 of the Consolidated Complaint and refers the Court to the referenced report for a full and complete statement of its content.

190. Mylan denies the allegations in Paragraph 190 of the Consolidated Complaint and refers the Court to the referenced report for a full and complete statement of its content.

191. Mylan denies the allegations in Paragraph 191 of the Consolidated Complaint and refers the Court to the referenced report for a full and complete statement of its content.

192. Mylan denies the allegations in Paragraph 192 of the Consolidated Complaint and refers the Court to the referenced report for a full and complete statement of its content.

193. Mylan denies the allegations in Paragraph 193 of the Consolidated Complaint.

194. Mylan denies the allegations in Paragraph 194 of the Consolidated Complaint.

195. Mylan denies the allegations in Paragraph 195 of the Consolidated Complaint, except admits that Mylan entered into contracts with certain purchasers and refers the Court to those contracts for a full and complete statement of their terms.

196. Mylan denies the allegations in Paragraph 196 of the Consolidated Complaint, including the allegations contained in the referenced Exhibit A.

197 – 577. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 197 – 577 of the Consolidated Complaint and, therefore, denies those allegations.

578. Mylan denies the allegations in the first sentence of Paragraph 578 of the Consolidated Complaint, including the allegations contained in the referenced Exhibit A. Mylan denies the allegations in the second sentence of Paragraph 578, except admits that Exhibit B-27 purports to list the prescription drugs at issue in this action for Mylan. Mylan denies the

allegations in Paragraph 578, but admits that Plaintiffs have alleged claims without basis and as to which no relief should be granted.

579. Mylan denies the allegations in Paragraph 579 of the Consolidated Complaint, including the allegations contained in the referenced Exhibit B.

580. Mylan denies the allegations in Paragraph 580 of the Consolidated Complaint.

581. Mylan denies the allegations in Paragraph 581 of the Consolidated Complaint, including the allegations in the chart following Paragraph 580 of the Consolidated Complaint, and refers the Court to the referenced First DataBank information for a full and complete statement of its contents.

582. Mylan denies the allegations in Paragraph 582 of the Consolidated Complaint.

583. Mylan denies the allegations in Paragraph 583 of the Consolidated Complaint.

584. Mylan denies the allegations in Paragraph 584 of the Consolidated Complaint except admits that certain states have filed actions against Mylan alleging meritless and ill-informed claims, and Mylan refers to the pleadings in those actions as the best evidence of their content.

585. Mylan denies the allegations in Paragraph 585 of the Consolidated Complaint except Mylan admits that it has responded to written requests for information from the House Energy and Commerce Committee without any admission or finding of fault or liability.



586. Mylan denies the allegations in Paragraph 586 of the Consolidated Complaint except admits that the Commonwealth has served document requests on Mylan Laboratories Inc.

587. Mylan denies the allegations in Paragraph 587 of the Consolidated Complaint except admits that the Commonwealth of Massachusetts has filed an action against Mylan Laboratories Inc. alleging meritless and ill-informed claims, and Mylan refers to the pleadings in that action as the best evidence of their content.

588. Mylan denies the allegations in Paragraph 588 of the Consolidated Complaint.

589 – 769. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 589 – 769 of the Consolidated Complaint and, therefore, denies those allegations.

770. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 770 of the Consolidated Complaint and, therefore, denies those allegations. Mylan denies the allegations in the second sentence of Paragraph 770.

771. Mylan denies the allegations in Paragraph 771 of the Consolidated Complaint.

772. Mylan denies the allegations in Paragraph 772 of the Consolidated Complaint.

773. Mylan denies the allegations in Paragraph 773 of the Consolidated Complaint.

774. Mylan denies the allegations in Paragraph 774 of the Consolidated Complaint.

775. Mylan denies the allegations in Paragraph 775 of the Consolidated Complaint.

776. Mylan denies the allegations in Paragraph 776 of the Consolidated Complaint.

777. Mylan denies the allegations in Paragraph 777 of the Consolidated Complaint.

778. Mylan denies the allegations in Paragraph 778 of the Consolidated Complaint.

779. Mylan denies the allegations in Paragraph 779 of the Consolidated Complaint.

780. Mylan denies the allegations in Paragraph 780 of the Consolidated Complaint.

781. Mylan denies the allegations in Paragraph 781 of the Consolidated Complaint.

782. Mylan denies the allegations in Paragraph 782 of the Consolidated Complaint.

783. Mylan denies the allegations in Paragraph 783 of the Consolidated Complaint.

784. Mylan denies the allegations in Paragraph 784 of the Consolidated Complaint.

785. Mylan denies the allegations in Paragraph 785 of the Consolidated Complaint.

786. Mylan denies the allegations in Paragraph 786 of the Consolidated Complaint and refers the Court to the referenced article for a full and complete statement of its contents.

787. Mylan denies the allegations in Paragraph 787 of the Consolidated Complaint.

788. Mylan denies the allegations in Paragraph 788 of the Consolidated Complaint.

789. Mylan denies the allegations in Paragraph 789 of the Consolidated Complaint.

790. Mylan denies the allegations in Paragraph 790 of the Consolidated Complaint.

### **COUNT I**

791. Answering Paragraph 791 of the Consolidated Complaint, Mylan repeats, restates, realleges, and incorporates by reference its responses to the allegations in Paragraphs 1 – 790 of the Consolidated Complaint.

792 – 800. The Court dismissed Count I. Accordingly, Mylan is not required to respond to Paragraphs 792 through 800 of the Consolidated Complaint. To the extent a response is required, Mylan denies all allegations contained within Count I of the Consolidated Complaint.

### **COUNT II**

801. Answering Paragraph 801 of the Consolidated Complaint, Mylan repeats, restates, realleges, and incorporates by reference its responses to the allegations in Paragraphs 1 – 800 of the Consolidated Complaint.

802 – 807. The Court dismissed Count II. Accordingly, Mylan is not required to respond to Paragraphs 802 through 807 of the Consolidated Complaint. To the extent a response is required, Mylan denies all allegations contained within Count II of the Consolidated Complaint.

### **COUNT III**

808. Answering Paragraph 808 of the Consolidated Complaint, Mylan repeats, restates, realleges, and incorporates by reference its responses to the allegations in Paragraphs 1 – 808 of the Consolidated Complaint.

809. Mylan denies the allegations in Paragraph 809 of the Consolidated Complaint and refers the Court to the referenced statute for a full and complete statement of its terms.

810. Mylan denies the allegations in Paragraph 810 of the Consolidated Complaint.

811. Mylan denies the allegations in Paragraph 811 of the Consolidated Complaint.

812. Mylan denies the allegations in Paragraph 812 of the Consolidated Complaint.

813. Mylan denies the allegations in Paragraph 813 of the Consolidated Complaint.

### **COUNT IV**

814. Answering Paragraph 814 of the Consolidated Complaint, Mylan repeats, restates, realleges, and incorporates by reference its responses to the allegations in Paragraphs 1 – 813 of the Consolidated Complaint.

815 – 817. The Court dismissed Count IV. Accordingly, Mylan is not required to respond to Paragraphs 815 through 817 of the Consolidated Complaint. To the extent a response is required, Mylan denies all allegations contained within Count IV of the Consolidated Complaint.

#### **COUNT V**

818. Answering Paragraph 818 of the Consolidated Complaint, Mylan repeats, restates, realleges, and incorporates by reference its responses to the allegations in Paragraphs 1 – 817 of the Consolidated Complaint.

819 – 830. The Court dismissed Count V. Accordingly, Mylan is not required to respond to Paragraphs 819 through 830 of the Consolidated Complaint. To the extent a response is required, Mylan denies all allegations contained within Count V of the Consolidated Complaint.

#### **COUNT VI**

831. Answering Paragraph 831 of the Consolidated Complaint, Mylan repeats, restates, realleges, and incorporates by reference its responses to the allegations in Paragraphs 1 – 830 of the Consolidated Complaint.

832. Mylan denies the allegations in Paragraph 832 of the Consolidated Complaint.

833. Mylan denies the allegations in Paragraph 833 of the Consolidated Complaint.

834. Mylan denies the allegations in Paragraph 834 of the Consolidated Complaint.

835. Mylan denies the allegations in Paragraph 835 of the Consolidated Complaint and refers the Court to the referenced statutes for a full and complete statement of their terms.

836. Mylan denies the allegations in the first sentence of Paragraph 836 of the Consolidated Complaint and refers the Court to the referenced statute for a full and complete statement of its terms. Mylan denies the allegations in the second and third sentences of Paragraph 836.

837. Mylan denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 837 of the Consolidated Complaint and, therefore, denies those allegations.

838. Mylan denies the allegations in Paragraph 838 of the Consolidated Complaint.

839. Mylan denies the allegations in Paragraph 839 of the Consolidated Complaint.

## **COUNT VII**

840. Answering Paragraph 840 of the Consolidated Complaint, Mylan repeats, restates, realleges, and incorporates by reference its responses to the allegations in Paragraphs 1 – 839 of the Consolidated Complaint.

841. Mylan denies the allegations in Paragraph 841 of the Consolidated Complaint.

842. Mylan denies the allegations in Paragraph 842 of the Consolidated Complaint.

843. Mylan denies the allegations in Paragraph 843 of the Consolidated Complaint.

844. Mylan denies the allegations in Paragraph 844 of the Consolidated Complaint and refers the Court to the referenced statute for a full and complete statement of its terms.

845. Mylan denies the allegations in Paragraph 845 of the Consolidated Complaint.

### **COUNT VIII**

846. Answering Paragraph 846 of the Consolidated Complaint, Mylan repeats, restates, realleges, and incorporates by reference its responses to the allegations in Paragraphs 1 – 845 of the Consolidated Complaint.

847. Mylan denies the allegations in Paragraph 847 of the Consolidated Complaint.

848. Mylan denies the allegations in Paragraph 848 of the Consolidated Complaint.

849. Mylan denies the allegations in Paragraph 849 of the Consolidated Complaint.

850 – 858. Mylan denies that the Counties are entitled to judgment or any other relief as requested in the unnumbered “WHEREFORE” paragraph and Paragraphs 850 – 858 of the Consolidated Complaint.

**WHEREFORE**, Mylan demands judgment dismissing the Complaint with prejudice, and awarding reasonable expenses and costs incurred herein, and for such further relief as the Court deems just and proper.

**AFFIRMATIVE AND OTHER DEFENSES**

**First Defense**

The Consolidated Complaint fails to state a claim against Mylan upon which relief can be granted.

**Second Defense**

The Consolidated Complaint fails to satisfy the pleading requirements of Rule 8(a) of the Federal Rules of Civil Procedure.

**Third Defense**

Plaintiffs have not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Mylan as alleged in the Consolidated Complaint.

**Fourth Defense**

Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitations, and Plaintiffs are not entitled to any tolling of any limitations period.

**Fifth Defense**

Plaintiffs are estopped from claiming entitlement to the sum they seek because they have known throughout the relevant time period, from various public sources, including government reports provided to Plaintiffs, that the AWP published in industry sources were not what Plaintiffs now claim them to have been. Plaintiffs were aware that the reimbursement rates they and the State of New York Medicaid program were using to reimburse providers were greater than the estimated acquisition cost of these drugs, and knowingly set their reimbursement rates higher than estimated acquisition cost.



**Sixth Defense**

Plaintiffs fail to allege with particularity facts to support the fraud and/or fraudulent concealment allegations against Mylan as required by Rule 9(b) of the Federal Rules of Civil Procedure.

**Seventh Defense**

During the relevant time period, the New York State Medicaid Program did not regard AWP as anything other than a list or “sticker” price which it discounted for both branded and generic drugs when determining reimbursement rates.

**Eighth Defense**

Plaintiffs’ claims are barred, in whole or in part, by the doctrines of laches, estoppel, waiver, and unclean hands.

**Ninth Defense**

Plaintiffs’ claims are barred to the extent that the claims involve drugs reimbursed without reference to AWP.

**Tenth Defense**

Plaintiffs’ claims are barred, in whole or in part, because Mylan’s alleged statements, actions, or omissions were not the proximate cause of any alleged loss by Plaintiffs.

**Eleventh Defense**

Plaintiffs were negligent, careless, committed willful misconduct or were otherwise at fault in and about the matter referred to in the Consolidated Complaint and such conduct on the part of Plaintiffs caused and contributed to the injury complained of, if any actually occurred.

**Twelfth Defense**

Plaintiffs directed, ordered, approved and/or ratified Mylan’s conduct, and Plaintiffs are, therefore, barred from asserting any claims based thereon.

**Thirteenth Defense**

Any and all actions taken by Mylan with respect to any of the matters alleged in the Consolidated Complaint were taken in good faith and in accordance with established industry practice. Moreover, publishers, including First Data Bank, rather than Mylan, determine the AWP that they publish for drugs.

**Fourteenth Defense**

Plaintiffs' claims against Mylan are barred because Mylan has complied with all applicable regulations of the federal government and the State of New York.

**Fifteenth Defense**

Plaintiffs' claims are barred, in whole or in part, because any injuries sustained by Plaintiffs, if any, were the result of their own conduct or intervening or superceding acts or omissions of third parties.

**Sixteenth Defense**

Plaintiffs' claims against Mylan for damages are barred, in whole or in part, because Plaintiffs failed to mitigate and/or neglected to minimize their damages, and their failure to mitigate damages should proportionately reduce their recovery and the allocation of any fault, if any exists, attributable to Mylan.

**Seventeenth Defense**

Plaintiffs receive funding from the federal government for a percentage of the prescription drug reimbursements made under the New York Medicaid program. Any of Plaintiffs' recovery should be substantially if not entirely set off by appropriate percentages of those amounts and should also be reduced by any benefits and rebates provided by Mylan. Plaintiffs' claims against Mylan for damages are barred, in whole or in part, because Plaintiffs

would be unjustly enriched if allowed to recover any portion of the damages alleged in the Consolidated Complaint.

**Eighteenth Defense**

Mylan is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiffs with respect to the same alleged injuries.

**Nineteenth Defense**

Plaintiffs' claims for damages against Mylan are barred, in whole or in part, by the doctrine of consent and/or ratification to the extent that Plaintiffs have received and paid for pharmaceuticals manufactured, marketed and sold by Mylan after the filing of each Plaintiff's original complaint and after first learning of the information that forms the basis for the allegations in each Plaintiff's complaint.

**Twentieth Defense**

Any damages recovered by Plaintiffs must be limited by the applicable statutory ceilings on recoverable damages.

**Twenty-First Defense**

Plaintiffs fail to state a claim against Mylan sufficient to support an award for investigative costs, treble damages, attorneys' fees and/or legal fees.

**Twenty-Second Defense**

Plaintiffs' claims are barred, in whole or in part, by the doctrines of mistake and mutual mistake.

**Twenty-Third Defense**

The civil penalties sought against Mylan cannot be sustained because an award of the civil penalties sought by Plaintiffs would violate the United States Constitution, Excessive Fines

Clause of the Eighth Amendment, U.S. Const. amend. VIII, and the Due Process Clauses of the Fifth and Fourteenth Amendments, U.S. Const. amend. V and XIV, and the analogous provisions in the Constitution of the State of New York.

**Twenty-Fourth Defense**

Plaintiffs' claims are barred, in whole or in part, because they violate Mylan's rights under the Due Process and Ex Post Facto clauses of the United States Constitution and the analogous provisions of the Constitution of the State of New York insofar as Plaintiffs seek to impose liability retroactively for conduct that was not actionable at the time it occurred.

**Twenty-Fifth Defense**

The granting of relief prayed for in Plaintiffs' Consolidated Complaint is unconstitutional under the United States Constitution and Constitution of the State of New York in that it violates Due Process and Equal Protection guarantees, places an undue burden on interstate commerce, and violates Constitutional proscriptions against excessive fines.

**Twenty-Sixth Defense**

The granting of the relief prayed for in Plaintiffs' Consolidated Complaint is unconstitutional in that it would violate Mylan's right of commercial speech under the United States Constitution and Constitution of the State of New York.

**Twenty-Seventh Defense**

Plaintiffs have failed to join all persons and parties necessary for a just adjudication of the controversy.

**Twenty-Eighth Defense**

Any or all causes of action in Plaintiffs' Consolidated Complaint are barred because of the lack of privity between Plaintiffs and Mylan.

**Twenty-Ninth Defense**

Any or all causes of action in Plaintiffs' Consolidated Complaint are barred because the statutes upon which Plaintiffs rely are vague and ambiguous.

**Thirtieth Defense**

Plaintiffs' claims for injunctive relief against Mylan are barred by the doctrines of *in pari delicto* and/or unclean hands.

**Thirty-First Defense**

Plaintiffs' claims are barred, in whole or in part, because Mylan did not make any statements to Plaintiffs. As to any statement asserted against Mylan that Plaintiffs claim to be false or misleading, Mylan had no reasonable grounds to believe, and did not believe at the time such statements were made, that the statements were false or misleading.

**Thirty-Second Defense**

Plaintiffs' claims are barred, in whole or in part, by the political question and separation of powers doctrines.

**Thirty-Third Defense**

Plaintiffs' claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

**Thirty-Fourth Defense**

Plaintiffs' claims are preempted by the dormant Commerce Clause of the United States Constitution.

**Thirty-Fifth Defense**

Mylan did not owe any duty to Plaintiffs and did not breach any duty owed to Plaintiffs.

**Thirty-Sixth Defense**

Plaintiffs' claims are barred, in whole or in part, by the government contractor and similar defenses because the reimbursement system, including the use of AWP in excess of actual average prices, was designed and approved by Plaintiffs, along with the federal government and the State of New York, to serve their purposes.

**Thirty-Seventh Defense**

Plaintiffs' claims against Mylan are barred, in whole or in part, because they have suffered no damages as a result of the matters alleged in the Consolidated Complaint.

**Thirty-Eighth Defense**

Plaintiffs' claims for damages are barred, in whole or in part, because their alleged damages, if any, are speculative and because of the impossibility of the ascertainment and allocation of those alleged damages.

**Thirty-Ninth Defense**

To the extent equitable relief is sought, such claims cannot be sustained because the Plaintiffs have an adequate remedy at law.

**Fortieth Defense**

Plaintiffs' claims are barred, in whole or in part, by the filed rate doctrine.

**Forty-First Defense**

Plaintiffs have no standing or capacity to bring some or all of the claims raised in this suit to recover Medicaid expenditures or to seek injunctive relief.

**Forty-Second Defense**

Plaintiffs' claims against Mylan for injunctive relief were mooted by the passage of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

**Forty-Third Defense**

To the extent punitive damages are sought, Plaintiffs' punitive damages claims against Mylan: (1) have no basis in law or fact; (2) are not recoverable because the allegations of the Consolidated Complaint are legally insufficient to support a claim for punitive damages against Mylan; (3) cannot be sustained because the laws regarding the standards for determining liability for and the amount of punitive damages fail to give Mylan prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed, and are void for vagueness in violation of Mylan's Due Process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and the Constitution of the State of New York; (4) cannot be sustained because any award of punitive damages exceeding the limits authorized by the laws or other comparable laws would violate Mylan's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law and laws of the State of New York; (5) cannot be sustained because an award of punitive damages in this case, combined with any prior, contemporaneous, or subsequent judgments against Mylan for punitive damages arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of Mylan's products would constitute impermissible multiple punishments for the same wrong, in violation of Mylan's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the Constitution, common law, and statutory laws of the State of New York; (6) cannot be sustained because any award of punitive damages without the apportionment of the award separately and severally between or among the alleged joint tortfeasors, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate Mylan's Due Process and Equal Protection rights guaranteed by

the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law, and public policies of the State of New York; and (7) cannot be sustained because any award of punitive damages, which are penal in nature, without according Mylan the same protections that are accorded to all criminal defendants, including the protection against unreasonable searches and seizures, the privilege against self-incrimination, and the rights to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate Mylan's rights guaranteed by the Fourth, Fifth, and Sixth Amendment as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the Constitution, common law, and public policies of the State of New York.

#### **Forty-Fourth Defense**

To the extent punitive damages are sought, Plaintiffs' claims for punitive damages against Mylan cannot be sustained because an award of punitive damages by a jury that: (1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive damages award; (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part on the basis of invidiously discriminatory characteristics, including without limitation the residence, wealth, and corporate status of Mylan; (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; (5) is not properly instructed regarding Plaintiffs' burden of proof with respect to each and every element of a claim for punitive damages; and (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally



adequate and objective standards, would violate Mylan's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the Constitution, common law, and public policies of the State of New York.

**Forty-Fifth Defense**

To the extent punitive damages are sought, Plaintiffs' claims for punitive damages against Mylan cannot be sustained because an award of punitive damages that is subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount of punitive damages that may be imposed, would: (1) violate Mylan's Due Process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution; (2) violate Mylan's right not to be subjected to an excessive award; and (3) be improper under the Constitution, common law, and public policies of the State of New York.

**Forty-Sixth Defense**

Plaintiffs' claims are barred, in whole or in part, because Mylan did not retain any money belonging to the State of New York or to Plaintiffs as a result of any alleged overpayments.

**Forty-Seventh Defense**

Subject to confirmation during discovery, Mylan hereby reserves those affirmative defenses required to be specifically pled under Rule 8(b) of the Federal Rules of Civil Procedure not specifically pled above and incorporates them as if fully set forth in separate paragraphs. Mylan reserves the right to amend its answer to assert additional affirmative defenses and to supplement those asserted herein upon discovery of further information regarding the claims asserted in the Consolidated Complaint. These additional defenses cannot be asserted at this time because of the lack of detail in the Consolidated Complaint concerning Plaintiffs' claims.

**Forty-Eighth Defense**

Mylan Laboratories Inc. does not and has not conducted any business in New York and there is no basis for personal jurisdiction over Mylan Laboratories Inc. under New York law, and personal jurisdiction over Mylan Laboratories Inc. would be improper under the United States Constitution.

**Forty-Ninth Defense**

The Plaintiffs' claims are barred, in whole or in part, by the settlement agreement in connection with *FTC v. Mylan Laboratories Inc., et al.*, C.A. No. 98-CV-03114-TFH (D.D.C.) and *State of Connecticut v. Mylan Laboratories Inc., et al.*, C.A. No. 98-CV-03115-TFH (D.D.C.).

**Fiftieth Defense**

The Plaintiffs' claims are barred, in whole or in part, by the release of claims in connection with *FTC v. Mylan Laboratories Inc., et al.*, C.A. No. 98-CV-03114-TFH (D.D.C.) and *State of Connecticut v. Mylan Laboratories Inc., et al.*, C.A. No. 98-CV-03115-TFH (D.D.C.).

**Fifty-First Defense**

The Plaintiffs' claims are barred, in whole or in part, by an accord and satisfaction between Mylan and the State of New York in connection with *FTC v. Mylan Laboratories Inc., et al.*, C.A. No. 98-CV-03114-TFH (D.D.C.) and *State of Connecticut v. Mylan Laboratories Inc., et al.*, C.A. No. 98-CV-03115-TFH (D.D.C.).

**Fifty-Second Defense**

The Plaintiffs' claims are barred, in whole or in part, by Mylan's payment in connection with *FTC v. Mylan Laboratories Inc., et al.*, C.A. No. 98-CV-03114-TFH (D.D.C.) and *State of Connecticut v. Mylan Laboratories Inc., et al.*, C.A. No. 98-CV-03115-TFH (D.D.C.).

**Fifty-Third Defense**

The Plaintiffs' claims are barred, in whole or in part, by the waiver of claims in connection with *FTC v. Mylan Laboratories Inc., et al.*, C.A. No. 98-CV-03114-TFH (D.D.C.) and *State of Connecticut v. Mylan Laboratories Inc., et al.*, C.A. No. 98-CV-03115-TFH (D.D.C.).

**Fifty-Fourth Defense**

To the extent Plaintiffs have obtained or obtain recovery in any other action or proceeding predicated on the same factual allegations, they are barred from seeking recovery against Mylan based on the Consolidated Complaint pursuant to the doctrines of res judicata and collateral estoppel and the prohibition on double recovery for the same injury.

**Fifty-Fifth Defense**

Some or all of the Plaintiffs' claims against Mylan arise from the State of New York's failure to follow its federal and state statutory and regulatory obligations to properly establish appropriate reimbursement rates.

**Fifty-Sixth Defense**

The Plaintiffs' claims are barred, in whole or in part, because the Plaintiffs have not suffered any actual injury or damage as a result of any conduct alleged as a basis of this lawsuit.

**Fifty-Seventh Defense**

The Plaintiffs' claims are barred, in whole or in part, because Mylan's alleged conduct was reasonable and based on independent, legitimate business and economic justifications.

**Fifty-Eighth Defense**

The Plaintiffs' claims are barred, in whole or in part, because any and all of Mylan's actions alleged by the Plaintiffs were lawful, justified, pro-competitive, carried out in furtherance of Mylan's legitimate business interests, and constitute bona fide business competition.

**Fifty-Ninth Defense**

The Plaintiffs' claims are barred, in whole or in part, by the First Amendment of the United States Constitution and the analogous provisions of the Constitution of the State of New York.

**Sixtieth Defense**

The Plaintiffs' claims against Mylan are misjoined with Plaintiffs' claims against other defendants and must be severed.

**Sixty-First Defense**

Plaintiffs' claims against Mylan are barred, in whole or in part, by the existence of and terms of the written rebate agreement between Mylan and the Secretary of the Department of Health and Human Services ("HHS"), on behalf of HHS and all States, entitled, "Rebate Agreement Between the Secretary of Health and Human Services and the Manufacturer Identified in Section XI of this Agreement", which was entered into pursuant to 42 U.S.C. § 1396r-8.

**Sixty-Second Defense**

Mylan hereby gives notice that it intends to rely upon any other additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserves its right to amend its answer to assert such defense. Mylan also reserves the right to assert such other and related defenses as may become available in the event of a determination that the action, or some part thereof, is governed by the substantive law of a state other than New York and/or any other State which is or becomes relevant in the course of this multidistrict litigation.

**Sixty-Third Defense**

Mylan hereby adopts and incorporates by reference, as if fully set forth herein, any affirmative defenses listed by any other defendant in its answer to Plaintiffs' Consolidated Complaint to the extent that such defenses are factually and/or legally consistent with Mylan's position.

WHEREFORE, Mylan prays for judgment: (i) dismissing the Consolidated Complaint in its entirety; (ii) awarding to Mylan costs and fees incurred in this action; and (iii) granting to Mylan such other and additional relief, both legal and equitable, as justice and the nature of the cause may require.

Dated: October 26, 2007

Respectfully submitted,

KELLEY DRYE & WARREN LLP

By: /s/ Neil Merkl  
William A. Escobar (admitted *pro hac vice*)  
Neil Merkl (admitted *pro hac vice*)  
Christopher C. Palermo (admitted *pro hac vice*)

101 Park Avenue  
New York, NY 10178  
(212) 808-7800 (telephone)  
(212) 808-7897 (facsimile)

Attorneys for Defendants  
Mylan Laboratories Inc.,  
Mylan Pharmaceuticals Inc. and  
UDL Laboratories, Inc.

**CERTIFICATE OF SERVICE**

I certify that a true and correct copy of the foregoing Defendants Mylan Laboratories Inc., Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc.'s Answer to Plaintiffs' Consolidated Complaint was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on October 26, 2007, a copy to LexisNexis File & Serve for posting and notification to all parties.

\_\_\_\_\_/s/ Neil Merkl